

NUPLAZID™

(pimavanserin) tablets

ABOUT NUPLAZID

NUPLAZID (pimavanserin) is the first and only medication approved by the U.S. Food and Drug Administration (FDA) for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. An estimated 40 percent of patients have PD psychosis, with lifetime prevalence in excess of 50 percent.^{i,ii}

Before NUPLAZID, there was no FDA-approved treatment in the United States for this condition. Physicians would often treat the condition by reducing the very medications that are used to treat the motor symptoms of Parkinson's disease, which could worsen motor function for the patient. Physicians could also choose to treat the condition with other antipsychotics, which are not approved by the FDA for this indication.ⁱⁱⁱ

NUPLAZID is a non-dopaminergic selective serotonin inverse agonist preferentially targeting 5-HT_{2A} receptors that are thought to play an important role in Parkinson's disease psychosis. NUPLAZID is administered orally, once a day.



NUPLAZID CLINICAL DATA

In a pivotal Phase III clinical trial of 199 patients with PD psychosis (the -020 Study), NUPLAZID significantly reduced the frequency and severity of psychotic symptoms compared to placebo on the Scale of Assessment of Positive Symptoms – Parkinson's Disease (SAPS-PD). Due to its non-dopaminergic and selective mechanism of action, this benefit was achieved without impairing motor function compared to placebo.

The most common adverse reactions ($\geq 5\%$ and twice the rate of placebo) in this study were peripheral edema (7% NUPLAZID vs. 3% placebo) and confusional state (6% NUPLAZID vs. 3% placebo). Results of the -020 Study were published in *The Lancet*.

Important Safety Information and Indication for NUPLAZID™ (pimavanserin) tablets

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.

INDICATIONS AND USAGE

NUPLAZID is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

QT Interval Prolongation: NUPLAZID prolongs the QT interval. The use of NUPLAZID should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval including Class 1A antiarrhythmics or Class 3 antiarrhythmics, certain antipsychotic medications, and certain antibiotics.

See additional Important Safety Information on page 2

ABOUT ACADIA PHARMACEUTICALS

ACADIA is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. Please visit www.acadia-pharm.com for more information.

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NUPLAZID should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and presence of congenital prolongation of the QT interval.

Adverse Reactions: The most common adverse reactions ($\geq 2\%$ for NUPLAZID and greater than placebo) were peripheral edema (7% vs 2%), nausea (7% vs 4%), confusional state (6% vs 3%), hallucination (5% vs 3%), constipation (4% vs 3%), and gait disturbance (2% vs <1%).

Drug Interactions: Strong CYP3A4 inhibitors (eg, ketoconazole) increase NUPLAZID concentrations. Reduce the NUPLAZID dose by one-half.

Strong CYP3A4 inducers may reduce NUPLAZID exposure, monitor for reduced efficacy. Increase in NUPLAZID dosage may be needed.

Renal Impairment: No dosage adjustment for NUPLAZID is needed in patients with mild to moderate renal impairment. Use of NUPLAZID is not recommended in patients with severe renal impairment.

Hepatic Impairment: Use of NUPLAZID is not recommended in patients with hepatic impairment. NUPLAZID has not been evaluated in this patient population.

Pediatric Use: Safety and efficacy have not been established in pediatric patients.

Dosage and Administration: Recommended dose: 34 mg per day, taken orally as two 17 mg tablets once daily, without titration.

- i Fenelon G, Mahieux F, Huron R, et al. Hallucinations in Parkinson's disease: prevalence, phenomenology and risk factors. *Brain*. 2000.
- ii Forsaa EB, Larsen JP, Wentzel-Larsen T, et al. A 12-Year Population-Based Study of Psychosis in Parkinson Disease. *Arch Neurol*. 2010.
- iii Goldman J, Holden S. Treatment of Psychosis and Dementia in Parkinson's Disease. *Curr Treat Options Neurol*. 2014.

